

## **REMARKS/ARGUMENTS**

**In view of the foregoing amendments and following remarks, favorable reconsideration of the pending claims is requested.**

### **1. Claim amendments**

Claim 35 has been limited to the specific modified Tat-encoded polypeptides which are supported by Table 1 (page 44) as indicated by the Examiner on pages 3-4 of the instant Office Action.

Therefore, paragraph b) has been limited to the modified Tat-encoded polypeptides wherein the seven cysteines located in positions 22, 25, 27, 30, 31, 34 and 37 of Tat amino acid sequence are either substituted with a hydrophobic amino acid chosen from: Leucine, Isoleucine, Phenylalanine, Tryptophan and Tyrosine or modified with the hydrophobic group S-tert-butyl.

The new paragraph c) has been limited to the modified Tat-encoded polypeptides wherein the cysteines located in positions 22, 34 and 37 of Tat amino acid sequence are substituted with a serine and the cysteines located in positions 25, 27, 30 and 31 of said sequence are modified with the hydrophobic group S-tert-butyl.

The paragraph c) of claim 35 has been renumbered paragraph d).

Claims 36, 37, 45 and 47 have been adapted to the new claim 35.

Claims 40 and 41 have been cancelled.

Support for the amended paragraph b) is found in claims 35 and 41 and support for the new paragraph c) is found in claims 35, 40, 41 and on page 11, lines 19 to 23 of the specification.

No new matter has been added.

### **2. Response to the Rejection under 35 USC § 112 second paragraph**

Claims 35-53, 55-57 and 67-79 were rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement.

The Office Action on pages 3-4 acknowledged that the specification provides written support for the modified Tat-encoded polypeptide wherein: (1) all seven cysteine residues recited in the claims are mutated to Leucine, Isoleucine, Phenylalanine,

Tryptophan and Tyrosine or derivitized by StBu, and (2) the triple mutated, StBu-modified tat-encoded specie of Table 1 (page 44).

The claims have been amended to provide for an HIV immunogenic composition comprising at least one isolated, stabilized Tat antigen resistant to proteolytic degradation selected from the group consisting of:

- a) a complex Tat/ligand comprising at least an HIV Tat protein or a Tat fragment of at least 11 amino acids capable of inducing an anti-Tat specific humoral and/or cellular immune response in humans, and a non-metal ligand of Tat,
- b) an artificial variant of an HIV Tat protein or of a Tat fragment of at least 11 amino acids capable of inducing an anti-Tat specific humoral and/or cellular immune response in humans, wherein the seven cysteines located at positions 22, 25, 27, 30, 31, 34 and 37 of the Tat amino acid sequence are modified with the hydrophobic group S-tert-butyl or substituted with a hydrophobic amino acid chosen from: Leucine, Isoleucine, Phenylalanine, Tryptophan and Tyrosine,
- c) an artificial variant of an HIV Tat protein or of a Tat fragment of at least 11 amino acids capable of inducing an anti-Tat specific humoral and/or cellular immune response in humans, wherein the cysteines located at positions 22, 34 and 37 of the Tat amino acid sequence are substituted with a serine and the cysteines located at positions 25, 27, 30 and 31 of said sequence are modified with the hydrophobic group S-tert-butyl, and
- d) a complex between the artificial variant of a Tat protein or of a Tat fragment defined in b) or c), and a non-metal ligand of Tat.

In view of this amendment, Applicant respectfully submits that the rejection to the claims has been overcome, and withdrawal of the rejection is respectfully requested.

### **Conclusion**

In view of the claim amendments and the foregoing comments and accompanying evidence, it is submitted that all outstanding issues have been overcome and the claims of this application are in condition for immediate allowance. Favorable reconsideration by the Examiner and formal notification of the allowability of the claims are solicited.

Appl. No.: 10/599,448  
Amdt. dated 12/29/2011  
Reply to Office Action of 09/29/2011

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefor (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'T. Balts', is written over the typed name.

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